TECHNICAL SUPPORT SECTION TOXICOLOGY REVIEW - I

Disinfectants Branch

IN 10/6/81 OUT 10/9/81

Reviewed by James E. Wilson, Jr. Date 10/8/81

EPA Reg. No. or File Symbol 1677-IO (89)

EPA Petition or EUP No.

Date Division Received 9/25/81

Type Product(s): I, (D), H, F, N, R, S

Data Accession No(s). 246001

Product Mgr. No. 32 (Castillo)

Product Name(s) Bac-Flush

Company Name(s) Economics Laboratories, Inc.

Submission Purpose Tox. Data - Resubmission

Chemical & Formulation Concentrate

Active Ingredient(s):	%
Polyethyoxy polypropoxy polyethoxy ethanol-iodine complex	25.8
Phosphoric Acid	25.0

300.0 Introduction

Economics Laboratory submitted acute toxicology data on the formulation which was evaluated in a review dated 7/9/81. In that review the acute oral study was found to be unacceptable due to 3/5 female deaths at 5 g/kg.

Subsequent to the review, the registrant contacted Dr. Engler, Branch Chief of the Disinfectants Branch, who, according to Economic's letter dated 9/23/81, "agreed that a repeat of the test on five female rats would suffice." Consequently, the registrant is submitting this study on females only.

301.0 Data Summary

301.1 Brief Description of Study

Acute Oral Toxicity in Female Rats. Report by Raltech Scientific Services, submitted to Economics Laboratory, Madison, WI 53707, dated September 15, 1981. (Accession No. 246001).

301.2 Study Summary

1. Method

Five groups of female albino rats, 8 rats per group were fed via gavage doses of 2.05, 3.20, 4.00, 5.00 and 6.25 g/kg of the undiluted test article. Animals were observed 3 times on the days of dosing and daily thereafter for 14 days for pharmacotoxic signs. Body weights were taken on day 0 and all survivers were again weighed on days 7 and 14. All rats received a gross necropsy examination.

2. Results

The mortality was as follows:

Dose	Dead/Dosed
2.05	0/8
3.20	1/8
4.00	5/8
5.00	7/8
6.25	7/8

Hypoactivity, ataxia, decreased limb tone, bradycardia and urine stained abdomens were noted. These signs were generally of short duration (2 days or less). The deaths occurred within 2 days and the stomachs of most of the the rats which died contained a brown liquid material.

3. Conclusion

The acute oral LD_{50} of the chemical in female rats is 4.13 (3.45-4.78) g/kg.

302.0 Recommendations

302.1 Safety Supported by Data

Based on the data reviewed herein, the product should be placed in toxicity category 3 for acute oral toxicity.

302.3 Other Considerations

Please refer to my previous review for other toxicity categories and recommended precautionary labeling.

No change in labeling is required by this study.